K103568

Coloplast

3 510(k) Summary

DEC 2 2 2010

510(k) Owner/SUBMITTER	Coloplast A/S Holtedam 1 Humlebaek 3050 - Denmark
CONTACT PERSON	Janell A. Colley Coloplast Corp 1601 West River Road North Minneapolis, Minnesota 55411 USA
DATE PREPARED	20 December 2010
CLASSIFICATION	Polymeric Surgical Mesh (Product Code FTL) is a Class II device per 21 CFR 878.3300
COMMON NAME	Polymeric Surgical Mesh
PROPRIETARY NAME	Restorelle™ polypropylene mesh
PREDICATE DEVICE	• K092207 – Restorelle • K041632 & K053361 - Minimesh (Mpathy Medical Ltd)
DEVICE DESCRIPTION	Restorelle is a non-absorbable polypropylene mesh constructed from knitted monofilaments of extruded polypropylene. Restorelle polypropylene mesh is constructed using a warp-knit process that permits the mesh to be cut into desired shape or size without unraveling. It maintains excellent isotropic properties arising from its knitted construction. Restorelle polypropylene mesh has the necessary strength, flexibility, durability and surgical adaptability properties which permit the correct adaptation to the various stresses encountered in the body. The device is supplied sterile.
INDICATIONS	Restorelle polypropylene mesh may be used for the repair of abdominal wall hernia, including inguinal, femoral, and incisional, and uterovaginal prolapse and other fascial deficiencies that require support material. It may be used in open or laparoscopic abdominal procedures or for repair by the vaginal route.
TESTING	The components of the Restorelle device have been subjected to biocompatibility and mechanical testing and are substantially equivalent to the predicate Restorelle (K092207) and Minimesh devices (K041632 & K053361).
TECHNOLOGICAL CHARACTERISTICS	Restorelle polypropylene mesh has the same intended use, general design, material and fundamental scientific technology as the predicate Restorelle polypropylene mesh device (K092207).
Summary Of The Nonclinical Tests Submitted	In vitro (bench) tests: Retention, Mechanical, Mass density testing
Summary Of Clinical Tests Submitted (As Applicable)	Not applicable
Conclusions Drawn From The Nonclinical And Clinical Tests	The device has been subjected to in-vitro testing which demonstrate the ability of the device to adequately permit correct adaptation to the various stresses encountered in the body during normal clinical use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Coloplast A/S
% Coloplast Corporation
Ms. Janell A. Colley
1601 West River Road N
Minneapolis, Minnesota 55411

DEC 2 2 2010

Re: K103568
Trade/Device Name: Restorelle Polypropylene Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: December 3, 2010
Received: December 6, 2010

Dear Ms. Colley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Coloplast

2 Statement of Indications for Use

Indications for Use

DEC 2 2 2010

510(k) Number (if known): K103568

Device Name: Restorelle Polypropylene Mesh

Indications for Use:

Restorelle polypropylene mesh may be used for the repair of abdominal wall hernia, including inguinal, femoral, and incisional, and uterovaginal prolapse and other fascial deficiencies that require support material. It may be used in open or laparoscopic abdominal procedures or for repair by the vaginal route.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103568